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(54) **Nasal ventilation cannula.**

(57) A nasal positive airway pressure device is provided having a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross-section outside the patient's nostril to a substantially oval cross-section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the side wall of the cannula. The nasal members are connected to one or more flexible hoses which, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to the each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The tapered tip configuration, soft inflatable cuffs and adjustable positioning of the nasal members and tip provide a device which is more comfortable to the user. A variable diameter orifice for nasal positive airway pressure treatment is also contemplated.

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housing and by mounting the elements in slots permitting selective lateral positioning of the elements with respect to each other. Flexible bellows-type corrugated sections can be provided in each of the elements and/or in appropriate positions in the plenum housing so as to add further ranges of flexibility and adjustability. The nares elements are fabricated from relatively soft, deformable, shape-retaining synthetic resin material permitting manual deformation and alteration of the effective shape and position of the elements. Trimble discloses a harness to be worn on a patient's head with flexible mask-retaining straps extending from the main harness strap to each side of the nasal puff. The harness assembly includes an elongated gas-conveying tube which is adapted for coupling with the inlet of the nasal puff and extends upwardly along the length of the bridge of the patient's nose and across the patient's forehead, terminating at the top of the patient's forehead. The tube is longitudinally bifurcated to divide the overall tube and present a pair of elongated, juxtaposed passageways, one of which is connected to a source of pressurized air and the other to a discharge tube for purging patient-generated CO_2 during exhalation). In an alternative embodiment Trimble discloses inflatable nares elements that are inserted into the nares and inflated manually by a separate source of pressure.

The Trimble nasal puff and harness assembly is an accepted apparatus for treatment of sleep apnea using nCPAP therapy. While the Trimble device is an improvement over prior mask structures, some patients continue to object to the Trimble structure as uncomfortable to wear. Studies show that a small but significant number of patients fail or are unable to continue nCPAP treatment due in at least some cases to the inconvenience or discomfort of wearing the presently available apparatus. See "The Effect of Positive Reinforcement on Hourly Compliance in Nasal Continuous Positive Airway Pressure Users with Obstructive Sleep Apnea", E.C. Fletcher and R.A. Luckett, Am. Rev. Respir. Dis. 1991; 143:936-941; "Maxillofacial Surgery and Nasal CPAP", R.W. Riley, N.B. Powell, C. Guilleminault, Chest 1990; 98:1421-1425; and "Surgical Treatment of Obstructive Sleep Apnea - Is Mandibular Surgery an Advance?", Chest 1990; 98:1315-1316.

Notwithstanding the general consensus that nasal positive airway pressure is an effective treatment for sleep apnea, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a substantial number of such patients could benefit from a nasal positive airway pressure apparatus which is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance. The device disclosed and claimed herein may find application to either nCPAP or BiPAP treatment.

SUMMARY OF THE INVENTION

In accordance with the present invention, a positive nasal airway pressure device is provided for treatment of sleep apnea. The device includes means for securing the device to the patient's head, i.e., a head strap or harness, a primary air tube to be connected to a source of air pressure in a known manner, at least one connector hose and a pair of nasal members connected to the at least one connector hose. The nasal members are connected to the connector hose. Preferably, the at least one connector hose comprises a pair of flexible hoses, which may be corrugated to enhance adjustability, and each nasal member is connected to one connector hose.

In a first embodiment of the invention the nasal member is a substantially U-shaped hollow body connected to the connector hose. The nasal member tapers to a substantially oval cross-section at the end distal to the connector hose. The nasal member includes an aperture in the sidewall of the member and an inflatable cuff surrounding the nasal member and overlying the aperture.

In a second embodiment of the invention the nasal member is a substantially rigid U-shaped hollow piece having a substantially circular cross-section throughout its length connected at one end to the connector hose and at the other to a tip member. The tip member is hollow and has a substantially circular cross-section at the end thereof connected to the nasal member. The tip member preferably tapers to a substantially oval cross-section at the opposite end to be inserted into the patient's nostril. The tip member may be friction fit to the nasal member and preferably is rotatably connected to the nasal member to facilitate adjustability. The tip includes an aperture through the side wall and an inflatable cuff surrounding at least a portion of the tip and overlying the aperture so that the interior space of the inflatable cuff communicates with the hollow interior of the tip. Preferably, the inflatable cuff extends to the end of the tip member and slightly beyond the end of the tip.

In use, the device is secured to the head of the user with the securing strap or harness. The flexible connector hoses are adjusted, as necessary, to position the nasal members for insertion into the patient's nares. Because the connector hoses are flexible the position of the nasal members may be adjusted by moving the hoses away from one another. If the hoses are corrugated the length of each hose also may be adjusted independent of the other. The nasal tip members further may be adjusted by rotating the tips relative to the nasal members so that the oval tip is aligned with the

end thereof;

Fig. 12 is a perspective view of the nasal tip member of the second embodiment of the invention with an inflatable cuff attached thereto, such as by the steps illustrated in Figs. 10-11;

Fig. 13A is a perspective view of a nasal member similar to the embodiment shown in Fig. 4, incorporating a variable orifice in accordance with an alternative embodiment of the invention, showing the variable orifice cap spaced from the nasal member;

Fig. 13B is a perspective view of the alternative embodiment of the invention shown in Fig. 13A, shown with the variable orifice cap mounted to the nasal member;

Fig. 14A is a perspective view of the variable orifice cap illustrating the orifice defining surface in the first, unexpanded condition to provide a first aperture diameter;

Fig. 14B is a perspective view of the variable orifice cap illustrating the orifice defining surface in the second, expanded condition to provide a second, enlarged aperture diameter;

Fig. 14C is a sectional view, in perspective, of the variable orifice cap of Fig. 14A; and

Fig. 14D is a sectional view, in perspective, of the variable orifice cap of Fig. 14B.

As those skilled in the art will appreciate, the foregoing drawings are illustrative only, and show the features of the invention in accordance with the invention as they relate to one another. The drawings are not drawn strictly to scale and should be interpreted accordingly.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, there is shown a nasal positive airway pressure device 10 in accordance with the invention. Device 10 generally consists of a primary tube 12, a connector piece 14, and a pair of nasal tubes 16, 18 each connected to a nasal member 20, 22. The apparatus may be secured to the head of the user with a head band 24 in a known manner. An adjustable support strap 26 preferably extends from the head band to aid in holding the nasal members adjacent the nose of the user. At least a portion of each nasal member 20, 22 defines a cannula configured and dimensioned to fit within the nares of a patient. Inflatable cuffs (see Figs. 3 and 4) surround at least a portion of each cannula to hold the cannula in position within the patient's nares in a manner to be explained below. Each nasal cannula preferably is substantially oval or elliptical in cross-section at the open tip thereof distal to nasal tube members 16, 18, and gradually tapers to a substantially cylindrical cross-section outside the patient's nares. The inflatable cuff surrounding each cannula is made of a relatively inelastic plastic material, and the interior space of the cuff communicates with the lumen of the cannula through an aperture in the cannula wall. As will be explained in greater detail below, the oval tip cross-section of the cannula in accordance with the invention provides greater patient comfort . In addition, the inflatable cuffs inflate under pressure during nCPAP or BiPAP treatment to hold the cannula within the nares in a manner which is more comfortable to the user than prior treatment devices.

The invention provides a positive airway pressure device which is easily secured to the head of a user and adjusted for maximum comfort to the user, a significant advantage over existing treatment devices.

Referring now to Figure 1, a front elevation view of a positive airway pressure device constructed in accordance with the invention mounted to the head of a user, primary tube 12 is made of a relatively flexible adjustable material, such as plastic, and is connected to a source of pressurized gas (not shown). The source of pressurized gas may be any source suitable for treating sleep apnea, and may be a source of pressurize air with or without supplements such as oxygen. The source of gas may provide continuous pressure as used in nCPAP treatment, or may provide varied levels of pressure such as used in BiPAP™ treatment.. In either case, the gas pressure typically is in the range of about 5 to about 15 centimeters of water. As shown in Figure 1, primary tube 12 may be corrugated in whole or in part to facilitate adjustment. Primary tube 12 typically would have an outer diameter of about .25 to .375 inches with an inner diameter of about .25 inches.

Referring again to Fig. 1, primary tube 12 is attached to connector 14 at a substantially cylindrical section 28 of connector 14. Primary tube 12 may be connected to cylindrical section 28 in any convenient manner suitable for coupling without substantial loss of gas pressure, such as by friction fit, gluing, welding, threading, bayonet mount or the like. Cylindrical section 28 is placed under head band 24 to hold the device in place relative to the user's head. Preferably, a foam pad 30 is placed between the cylindrical section and the forehead of the user for added comfort. As will be appreciated, foam pad 30 may be pre-attached to connector 14 for ease of use. Headband 24 preferably is a cloth or plastic strap with a simple fastening structure such as a hook and loop fastener, e.g., a Velcro™ fastener. Connector 14 further includes a chamber portion 32 having a pair of nasal tube connectors 34, 35 extending therefrom and adapted to be connected to nasal tubes 16, 18. As shown, connector 14 preferably is positioned adjacent the

nasal member, and tapers to a substantially oval cross-section at the distal end thereof. As will be appreciated, a circular cross-section at the connection of tip 250 to nasal member 222 facilitates a rotatable connection. Independent rotation of tips 250 allows the tips to rotate substantially about the axis of nasal member end 228 and, hence, the patient's nares to rotationally align the oval opening with the nasal opening.

Referring now to Figs. 5A-5C, the preferred design of removable nasal tip 250 will now be discussed. Fig. 5A is a side view of tip 250. Tip 250 preferably has a length "L" in the range of about .5 to 1.0 inch, and more preferably about .75 inch. Tip 250 preferably has a maximum outer diameter at proximal end 252 of about .4 to .5 inch, and more preferably about .45 inch. The second, distal end 254 preferably has a maximum outer diameter in the range of about .3 to .5 inch, and more preferably about .4 inch. Aperture 256 is a hole through the sidewall of tip 250 midway along the length of tip 250, and has a diameter in the range of about .020 to about .150 inch, and more preferably about .125 inch. As shown, the tip sidewall is tapered to gradually decrease in diameter from proximal end 252 to distal end 254.

Referring now to Fig. 5B, a distal end view of tip 250 along lines 5B-5B of Fig. 5A, proximal end 252 of tip 250 has a constant outer diameter defining a substantially circular cross-section. The outer diameter of the proximal end 254, however, defines a substantially oval cross-section indicated at 254A. As stated above, the major outer diameter 254D of the second, oval end 254A, shown vertically oriented in Fig. 5B, preferably is about .4 inch. The minor outer diameter 254d of the distal oval end 254 preferably is about .3 inch when the major outer diameter 254D is about .4 inch. The open distal end of tip 250 also is shown in Fig. 5B at 254B. As shown, the major inner diameter 254E of the opening at the distal end of tip 250 is aligned with the major outer diameter of tip end 254, with the minor inner diameter 254e substantially perpendicular to the major diameters. Preferably, major inner diameter 254E is about .29 inch when major outer diameter 254D is about .4 inch, and minor inner diameter 254e is about .2 inch when minor outer diameter 254d is about .3 inch.

Fig. 5D is a partial side cross-section view of tip 250 taken along lines 5D-5D of Fig. 5A. As there shown, proximal end 252 of the tip 250 has a substantially cylindrical recess 260 extending distally from the proximal end face 262 of tip 250. Cylindrical recess 260 is configured and dimensioned to receive the distal end 228 of nasal member 222. Surface 252A defines the outer surface of the proximal end 252 of tip 250. Surface 252B is the inner surface of cylindrical recess 260, and surface 252C is the inner surface of the proximal end 252 of tip 250. As will be explained in further detail below, inner surface 252B may be provided with one or more ribs, pins or other protrusions 264 to enhance positive friction fit between tip 250 and nasal member 222. Protrusions 264 may be continuous or discontinuous about the circumference of the tip 250.

Fig. 5C is a proximal end view of tip 250 taken along lines 5C-5C of Fig. 5A showing end face 262 and the circular cross-section of the proximal end 252 of tip 250. As shown, surfaces 252A, 252B and 252C are substantially circular in diameter at the proximal tip section with recess 260 between surfaces 252B and 252C. Also visible in Fig. 5C is oval aperture 254B at the distal end of tip 250.

Fig. 5E is a partial cross-section view taken along lines 5E-5E of Fig. 4, showing the proximal tip section 252 mounted onto nasal member 222 in accordance with a preferred friction fit construction. As shown, distal end 228 of nasal member 222 preferably has a reduced diameter section 270 extending distally therefrom configured to be inserted into cylindrical recess section 260 of tip member 250. Reduced diameter section 270 is friction fit within the cylindrical recess 260 of tip member 250 to hold tip 250 onto nasal member 222, and may include an annular recess 272 configured and dimensioned to receive annular ridge 264 on surface 252B to securely removably connect tip 250 to nasal member 222. As will be appreciated, given the substantially circular cross-section of nasal member end 228 and reduced diameter section 270, as well as the substantially circular cross-section of tip member proximal end 252 engaged therewith, tip 250 is rotatable relative to nasal member 222.

Figures 5A-5E illustrate tip 250 without inflatable cuff 258. It should be understood that in the preferred embodiment tip member 250 includes inflatable cuff 258, as shown in Figs. 4 and 12.

In use, tip members 250 are mounted to nasal members 222 which, in turn, are connected to nasal tubes 16, 18, connector 14 and primary air supply tube 12. The device is comfortably secured to the user's head with headband 24, and tips 250 are inserted into the patient's nares. Strap 42 may be inserted through strap-receiving members 38, 40 and attached to headband 24 to provide additional support for the device. The source of pressurized air (not shown) is activated to supply pressurized air to the device. The air source may be of the traditional continuous pressure type which provides a constant source of pressure to tip members 250, i.e., nCPAP treatment. Alternatively, the air source may be of the type which provides multiple levels of pressurized air, e.g., as used in BiPAP™ therapy. The pressurized air travels through the

bers 222 preferably also are rotatably connected to nasal tubes 16, 18, such as by a rotational snap-fit connection similar to that shown in Fig. 5E for connecting the nasal tip member to the nasal member. The use of flexible nasal tubes 16, 18 further facilitates adjustment of the device to accommodate a variety of differently spaced nares, as required by patient physiology. Because tips 250 and nasal members 222 are rotatably connected to each other the relative rotational position of tip members 250 and nasal members 222 advantageously may be adjusted in combination with the spacing of nasal tubes 16, 18 to achieve the optimum configuration and orientation for patient comfort. The use of corrugated flexible tubing further facilitates spacing of the tip members and optimization of the vertical distance from nasal members 222 to connector 14 to further accommodate the physiological structure of the patient.

The embodiment of Fig. 3 similarly provides several degrees of flexibility of adjustment to accommodate a patient's physiological structure. While the embodiment of Fig. 3 lacks rotational adjustment of tip member 250 relative to nasal member 222, the remaining flexibility of the nasal members relative to each other and to connector 14 are believed to constitute a significant advance in the art, particularly in view of the tapered tip configuration and oval open end of the nasal member of Fig. 3. In addition, it will be understood that nasal member 122 of Fig. 3 may be rotatably connected to the nasal tubes, such as by a snap fit connection of the type illustrated in Fig. 5E.

Because tip member 250 is removable from nasal member 222 the second embodiment is well suited to providing disposable tip members for hygienic reasons. Similarly, in the first embodiment of Fig. 3 the entire nasal member could be disposable. Alternatively, it is contemplated that the tip members could be washed and reused several times and replaced only infrequently.

Referring to Fig. 6, a further aspect of the invention relates to the configuration and fabrication of the inflatable cuff and attachment thereof to the nasal tip. Fig. 6 is a perspective view of a mandrel 80 for fabricating an inflatable cuff in accordance with the invention. Mandrel 80 has a first and second open ends 82, 84, and first and second substantially cylindrical sections 86, 88, respectively. Mandrel 80 also has an enlarged hollow central section 90 joined at either side thereof to sections 86, 88. Mandrel 80 is substantially symmetrical about the longitudinal axis of sections 86, 88. Referring now to Fig. 7, a side cross-section view of mandrel 80, mandrel section 86 preferably has an inner diameter "m" of about .35 inches adjacent enlarged central section 90, which dimension is slightly smaller than the outer diameter of distal end 254 of nasal tip member 250 (see Fig. 4). Mandrel section 88 preferably has an inner diameter "M" adjacent enlarged section 90 of about .42 inches, i.e., slightly smaller than the outer diameter of a portion of nasal tip member 250 at a point proximal of the distal end 254. Central section 90 is connected to sections 86, 88 at smooth rounded transition zones 92 and has a maximum width "c" of about .40 inch and a maximum inner diameter C of about .80 inch.

The manner in which cuff 250 may be fabricated using mandrel 80 will now be explained with reference to Figs. 8A and 8B. Fig. 8A is a cross-section view of mandrel 80 similar to Fig. 7 but with a thermoplastic tube 100 inserted therein. Tube 100 has an outer diameter on the order of but slightly smaller than the inner diameter of mandrel sections 86, 88 to facilitate insertion and removal of the tube. Preferably, tube 100 is a polyurethane plastic tube having a wall thickness on the order of about 2 to 6 mm and preferably about 4 mm. With tube 100 inserted into the mandrel, heat is applied to raise the temperature of at least at the central section of the tubing, or alternatively the entire tubing to a temperature above the glass transition temperature of the plastic but below the melting point of the plastic. As will be appreciated, heating the tubing to such a temperature allows the plastic to be deformed as desired without destroying the plastic material. Heating of the tubing may be accomplished in any number of ways, such as applying heat to the mandrel by passing hot air or liquid over the exterior of the mandrel or applying heat directly to the mandrel, e.g., by thermal conduction or electrical resistance, or by passing hot air or liquid through the mandrel and/or tube. Preferably, heat is applied to the exterior of the central section of the mandrel so as to heat that section of the adjacent tube. One end of the tube is sealed off before or during heating, and when the desired temperature is reached pressurized air or liquid is applied to the open end of the tube. The pressurized air or liquid applied to the tube also may be heated. Applying pressure to the heated tube in this manner causes the tube to expand to conform to the shape of the mandrel, as shown in Fig. 8B. In particular, the tube expands in the area adjacent the central section of the mandrel to form a bulbous region 102 of tubing connected to two substantially cylindrical tube sections. The bulbous region of the tubing conforms substantially to the shape of the mandrel center section. As will be appreciated, expanding the tube in this manner will cause the wall thickness of bulbous region 102 to thin out, reaching a minimum thickness at the maximum diameter "C" of the central section. Preferably, expanded bulbous region 102 of the tube 100 has a wall thickness of about 1 to 2 mm at the

member;

at least one aperture in each said cannula member providing gaseous communication between said cannula lumen and said inflatable cuff, each said cuff inflating when air pressure is applied to said cannula lumen;

means for supplying positive gas pressure to said lumen.

2. The device of claim 1 wherein said means for supplying positive gas pressure comprises a source of continuous positive air pressure.

3. The apparatus of claim 1 wherein said means for supplying positive gas pressure comprises a source providing at least two different gas pressures at different times.

4. The device of claim 1 further comprising means for adjusting the relative position of said cannula members.

5. The device of claim 1 wherein each said cannula member comprises a nasal tip member rotatably mountable to a nasal member.

6. The device of claim 5 wherein each nasal tip member has a substantially oval first open end, a substantially circular second open end, and a tapered body section between said first and second ends, and said at least one aperture is through the sidewall of said tapered body section, said inflatable cuff surrounding at least a portion of said tapered body section and enclosing said aperture, said substantially circular second open end rotatably mountable to said nasal member.

7. The device of claim 6 further comprising a pair of nasal members and a pair of flexible nasal tubes connected at a first end thereof to said nasal members, said flexible nasal tubes connected at a second end thereof to a source of pressurized air.

8. The apparatus of claim 7 wherein said flexible tubes are expandable corrugated tubes.

9. The apparatus of claim 1 wherein each said cannula member includes at least one vent hole spaced from said cannula member first portion.

10. The apparatus of claim 9 wherein said vent hole comprises a variable diameter orifice.

11. The apparatus of claim 1 further comprising securing means for securing said apparatus relative to the head of a patient.

12. In an apparatus for the treatment of sleep disorders having at least one nasal member with a tip portion to be inserted into the nares of a patient to supply positive air pressure to the nares of a patient, the improvement comprising a variable orifice member spaced from said tip portion, said variable orifice member defining a variable orifice assuming a first position having a first diameter at a first gas pressure and a second, expanded position having a second diameter greater than said first diameter at a second, increased gas pressure.

13. The variable orifice apparatus of claim 12 wherein said variable orifice member comprises an elastic material having an aperture therethrough.

FIG. 2

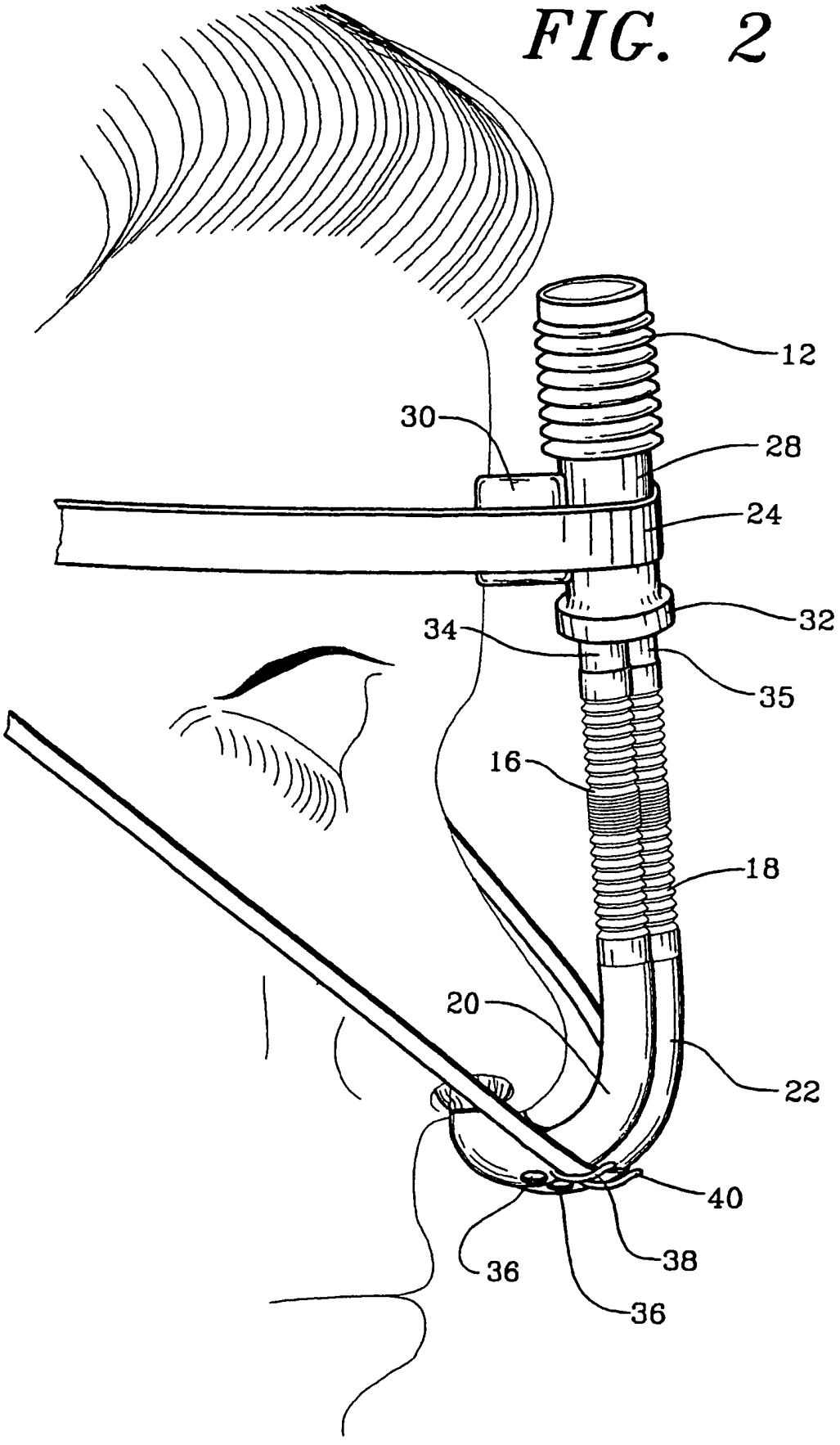

FIG. 4

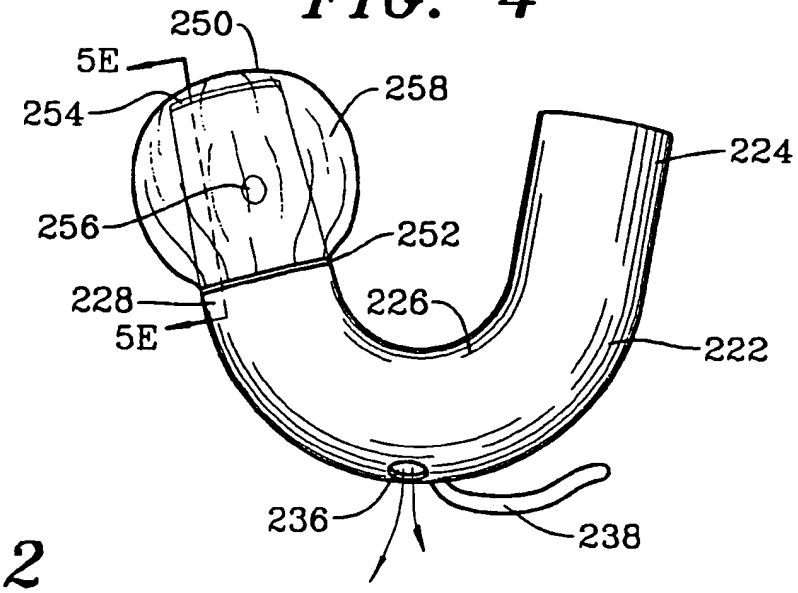

FIG. 12

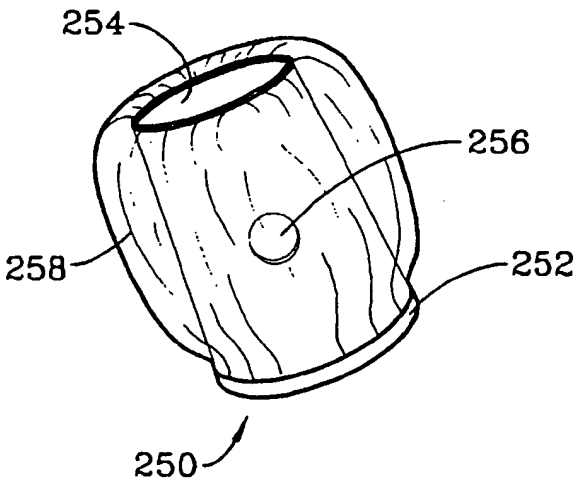

FIG. 5E

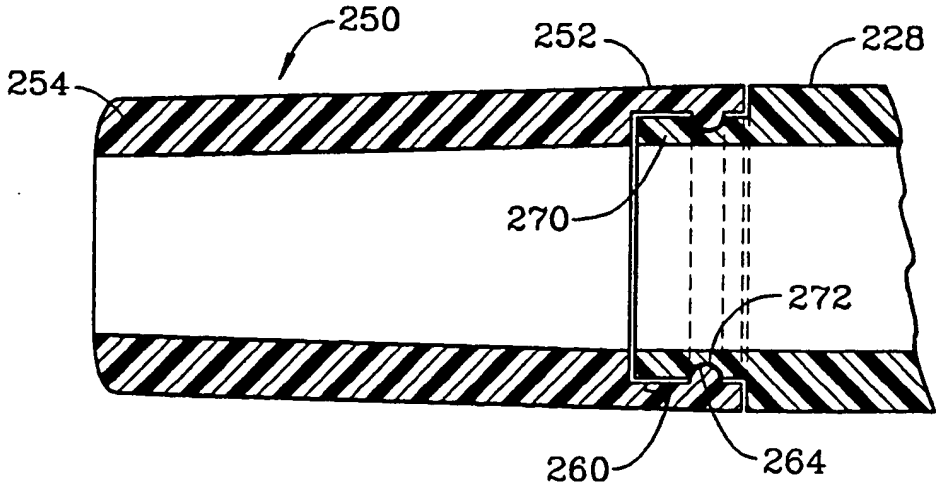

FIG. 6

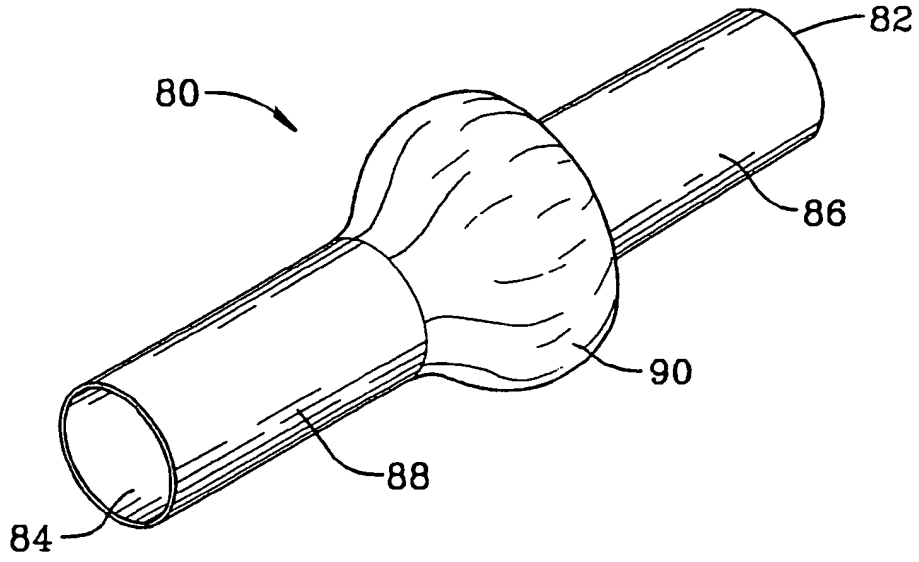

FIG. 7

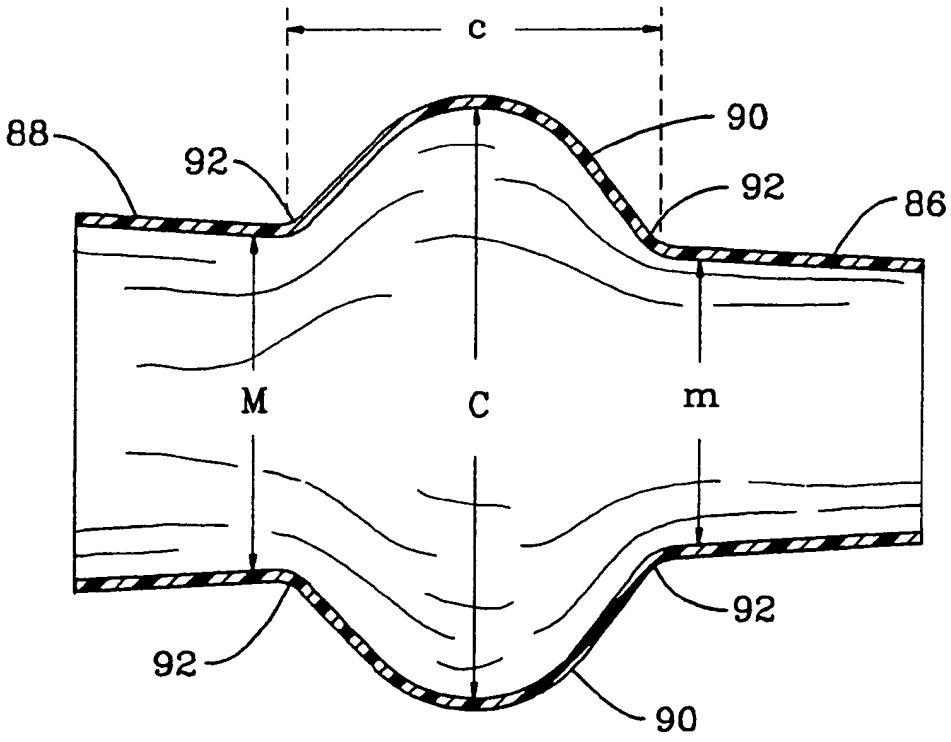

FIG. 9

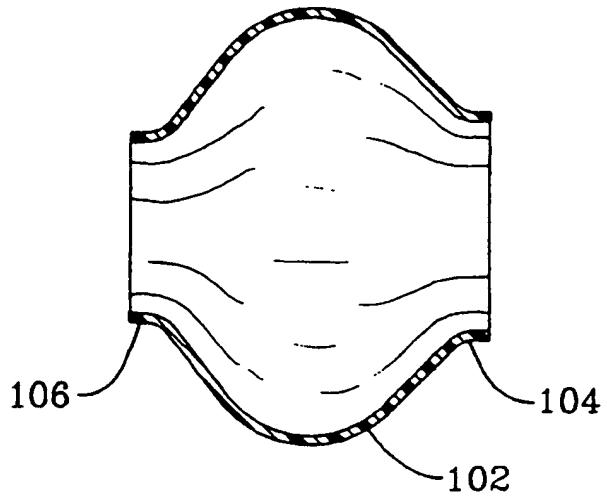

FIG. 10

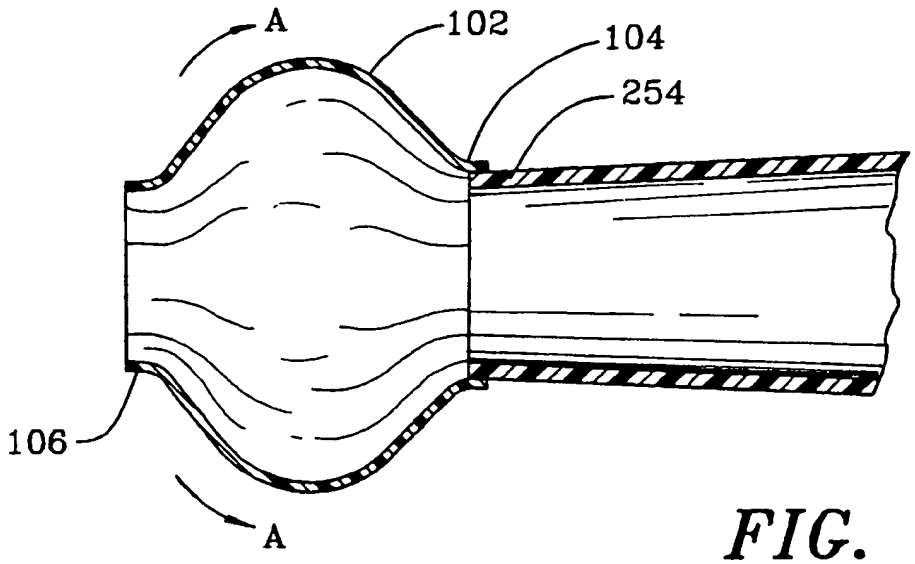

FIG. 11

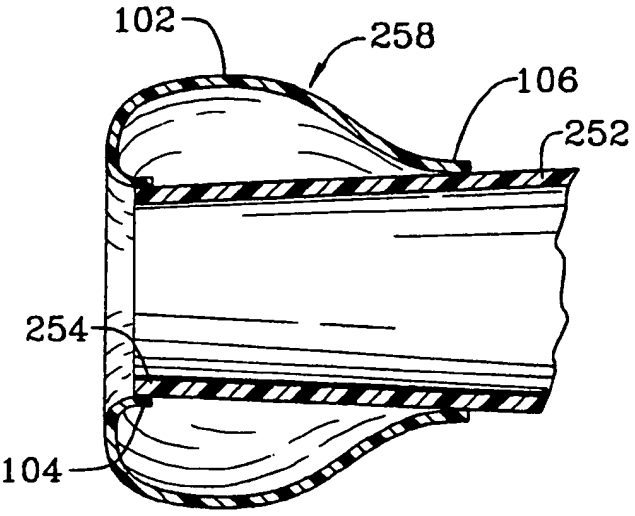

FIG. 14A

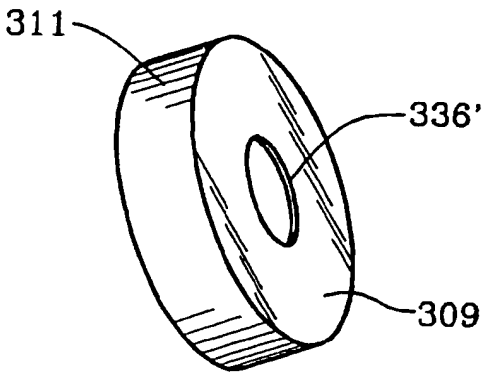

FIG. 14B

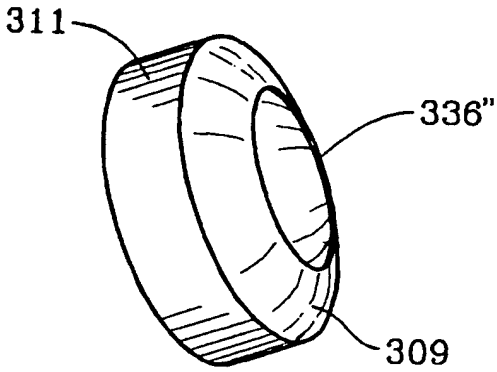

FIG. 14C

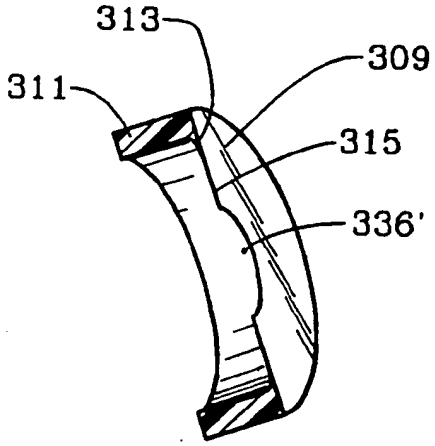

FIG. 14D